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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Petra Cirpus

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EXAMINER

KRUSE, DAVID H

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1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,303	Applicant(s) CIRPUS ET AL.	
	Examiner David H. Kruse	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 21 December 2007.
2. Those objections or rejections not specifically addressed in this Office action are withdrawn.
3. The amended Abstract is acceptable to the Examiner.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

5. Applicants are herein notified that claim 11 has been rejoined, as drawn to a method of using a claimed product.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
7. Claims 2 and 5 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 2 (c) and claim 5 (c), line 2, the limitation “at least about” renders the claim indefinite because it is unclear what the metes and bounds of the claim are.

8. The following is a quotation of the fourth paragraph of 35 U.S.C. § 112:

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

9. Claim 8 is rejected under 35 U.S.C. § 112, fourth paragraph, as failing to further limit the subject matter of a previous claim upon which it depends. Claim 8 fails to further limit the subject matter of claim 5.

10. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 2, 5, 8 and 13 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a method comprising transgenically expressing an oil synthesis enhancing protein having an amino acid sequence at least about 60% or 90% identical to SEQ ID NO: 2, a nucleotide sequence comprising at least 30 nucleotide of SEQ ID NO: 1, or having a nucleotide sequence at least 60% or 90% identical to SEQ ID NO: 1, an expression cassette comprising the nucleotide sequence and a genetically modified plant comprising said expression cassette.

Applicants describe nucleic acids encoding the amino acid sequence of SEQ ID NO: 2, having acetyltransferase activity.

Applicants do not describe the genus of nucleic acids having at least 60% or 90% identity to SEQ ID NO: 1 capable of enhancing oil synthesis nor do Applicants describe

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the genus of amino acid sequence at least about 60% or 90% identical to SEQ ID NO: 2 having this activity.

Hence, it is unclear that Applicants were in possession of the invention as broadly claimed. While a description of a representative number of species is adequate to represent an entire genus, wherein there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see MPEP 2163). A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4. In the instant case, there would have been a substantial variation within the genus of amino acid sequences, and their encoding nucleic acids, that enhance oil synthesis as broadly claimed.

12. Claims 2, 5, 8 and 13 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of increasing total oil content comprising transforming a plant cell with a nucleic acid encoding SEQ ID NO: 2, does not reasonably provide enablement a method of using nucleic acids having at least 60% or 90% identity to SEQ ID NO: 1 capable of enhancing oil synthesis or nucleic acids encoding an amino acid sequence at least about 60% or 90% identical to SEQ ID NO: 2 having this activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicants provide limited guidance on how to make and use nucleic acids that increase the total oil content in a plant organism or a tissue, organ, part, cell or

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propagation material thereof. Given, the breadth of the claims, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicants' invention to make and use such nucleic acids, given the broad, general function required in the coding sequence as claimed.

Claim Rejections - 35 USC § 102

13. Claims 5-9 remain rejected and claims 11 and 16-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Lassner, (WO 00/18889, 6 April 2000, SEQ ID NO: 217, SEQ ID NO: 225). This rejection is repeated for the reason of record as set forth in the last Office action mailed 26 June 2007. Applicant's arguments filed 21 December 2007 have been fully considered but they are not persuasive.

Applicants argue that while it is disclosed that the nucleic acids can be expressed in oil-producing plants (Lassner, page 14, lines 20-30), there is no disclosure that expression of any sequence, including SEQ ID NO: 225, would cause an increase in oil content in any plant or organism. Applicants argue that Example 8, noted by the Examiner, likewise fails to disclose an increase in oil content (page 9, 2nd paragraph of the Remarks). These arguments are not found to be persuasive. In response to applicant's argument that Lassner does not specifically disclose an increase in oil content in any plant or organism, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Applicants argue that Lassner does not disclose experimental data to support the hypothetical acyltransferase activity of the disclosed nucleic acid sequences Page 9, 3rd paragraph of the Remarks). This argument is not found to be persuasive. Failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation, *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999).

Applicants argue that in contrast to Lassner's disclosure, the claimed method recites a step of selecting the transgenic plant organism or a tissue, organ, part, cell or propagation material thereof based on the increased oil content. Applicants argue that Lassner does not disclose that transgenic expression would cause an increase in oil content; there is necessarily no disclosure of the claimed selection step (page 9, 4th paragraph of the Remarks). These arguments are not found to be persuasive as addressed above.

At claim 1, Lassner discloses an isolated DNA sequence encoding an acyltransferase wherein the amino acid sequence of SEQ ID NO: 216 meets the limitations of the claim. At claims 13-15, Lassner discloses a construct comprising said isolated DNA sequence and a plant cell and plant comprising the DNA construct. At page 12, lines 21-29, Lassner discloses that transcription initiation regions are preferentially expressed in a plant seed tissue, i.e. a seed-specific promoter sequence. Lassner discloses that the invention is directed to plant life involved in the production of vegetable oils for edible and industrial use (page 14, lines 22-23), hence Lassner

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discloses a method for producing oils by extracting from the transgenic plants. The limitations of instant claims 16-19 would appear to be inherent in the disclosure of Lassner.

Claim Rejections - 35 USC § 103

14. Claims 1-4 and 12-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lassner, (WO 00/18889, 6 April 2000, SEQ ID NO: 217, SEQ ID NO: 225). This rejection is repeated for the reason of record as set forth in the last Office action mailed 26 June 2007. Applicant's arguments filed 21 December 2007 have been fully considered but they are not persuasive.

The teachings of Lassner are outlined in the preceding rejection.

Lassner does not appear to explicitly teach a selecting step.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention to modify the teachings of Lassner to include a step of selecting plants transformed with the yeast acetyltransferase gene operably linked to a seed specific promoter wherein said plants transformed had increased oil content in their seeds. Lassner teaches that the particularly preferred plants of interest include plants that produce oil in their seed, and most especially preferred plants include *Brassica*, soybean and corn (see page 14, lines 24-27 and page 15, lines 4-7).

Applicants argue that one skilled in the art would not have been motivated to produce transgenic plant organism or a tissue, organ, part, cell or propagation material thereof, and to select those transgenic plant organism or a tissue, organ, part, cell or propagation material thereof for increased oil content, since the prior art provides no

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expectation that the transgenic plant organism or a tissue, organ, part, cell or propagation material thereof would have increased oil content (page 9, last paragraph of the Remarks). This argument is not found to be persuasive. In fact, Lassner particularly points one of ordinary skill in the art to transforming oilseed plants with the acetyltransferase genes taught. Lassner teaches that the purpose of the invention is for the development of alternative oil sources (page 1, lines 24-27). One of ordinary skill in the art would have understood this to mean, increased oil content.

Conclusion

15. This Office action is non-final in view of the new ground of rejection.

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

/David H Kruse/
Primary Examiner, Art Unit 1638
18 September 2008